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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,175	06/27/2003	Robert S. Golabek JR.	P-3488D1	8225
7590 04/14/2004				
David W. Highet, Esq. Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417		EXAMINER FUREMAN, JARED		
		ART UNIT PAPER NUMBER		
		2876		

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/608,175

Applicant(s)

GOLABEK ET AL.

Examiner

Jared J. Fureman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt is acknowledged of the amendment, filed on 3/22/2004, which has been entered in the file. Claims 14-20 are pending.

#### ***Claim Objections***

1. Claims 14 is objected to because of the following informalities: Claim 14, line 6: "the" (first occurrence) should be replaced with --a--, in order to avoid a lack of proper antecedent basis for "the sample". Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 14, 16, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Sodickson et al (US 3,656,473, cited by applicant).

Sodickson et al teaches a method for achieving accurate machine reading of information on a tube, said method comprising the steps of: providing a tube (15) having a closed bottom, an open top and a cylindrical side wall extending therebetween, said side wall being concentric about a longitudinal axis (see figures 2 and 3), said tube having an alignment key (38) non-concentrically disposed relative to said longitudinal axis; prior to collecting a sample in the tube (see column 1, line 69), providing an array of information on said cylindrical side wall (tube 15 includes a label 16 on the side wall of the tube) by use of a first apparatus (the marking unit, see column 1, lines 56-65)

such that said array of information is substantially parallel to said longitudinal axis and such that said array of information is at a specified angular position relative to said alignment key (see figures 2 and 3); collecting the sample of a biological fluid in said tube (see column 1, lines 69-74); and subsequent to collecting the sample, positioning said tube in a laboratory apparatus (see column 1, lines 69-74 and column 3, lines 42-46) distinct from said first apparatus such that said alignment key engages an alignment structure on said laboratory apparatus, thereby allowing said laboratory apparatus to read said information on said tube from a specified angular position relative to said alignment key (see column 1, lines 69-74 and column 3, lines 42-46); wherein said alignment key is a substantially planar notch (indent 38) extending into said tube, said laboratory apparatus comprising a planar fin (such as pin 37), said method comprising the step of engaging said notch over said fin; wherein said alignment key comprises a planar surface aligned at an acute angle to said longitudinal axis, said method comprising the step of positioning said planar surface of said tube against said planar surface on said laboratory apparatus (the wall(s) of the indent 38 represent a planar surface on the tube and the surface(s) pin 37 represents a planar surface on the laboratory apparatus) (see figures 2, 3, column 1 line 38 - column 2 line 7, and column 2 lines 29-47).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sodickson et al as applied to claim 14 above, and further in view of Isreeli (US 3,350,946, previously cited).

Sodickson et al fails to specifically teach the alignment key being a substantially planar fin lying in a plane passing through said longitudinal axis, the method comprising the step of engaging said fin in a slot formed in the laboratory apparatus.

Isreeli teaches a system and method, comprising a tube (12) having an alignment key (T-shaped projection 26), the alignment key being a substantially planar fin lying in a plane passing through a longitudinal axis of the tube, the method comprising the step of engaging said fin in a slot (52) formed in a laboratory apparatus (36) (see figures 1, 8-10, column 2 lines 16-27 and 66-68).

In view of Isreeli's teachings, it would have been obvious to one of ordinary skill in the art at the time of the invention to include, with the method as taught by Sodickson et al, the alignment key being a substantially planar fin lying in a plane passing through said longitudinal axis, the method comprising the step of engaging said fin in a slot formed in the laboratory apparatus, in order to avoid reducing the volume of the tube by placing the notch in the slot in the laboratory apparatus, rather than the tube.

6. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sodickson et al as applied to claim 14 above, and further in view of Erb et al (US 5,670,117, previously cited).

Sodickson et al fails to specifically teach wherein the array of information comprising a magnetic stripe, said step of reading said information comprising passing said tube in proximity to a magnetic reader for reading said information; wherein the array of information comprises a bar code, said step of reading said information comprising optically scanning said code; wherein said bar code is a linear bar code or a two dimensional dot matrix maxicode.

Erb et al teaches that one-dimensional bar codes, two-dimensional bar codes, magnetic strips, and printed alphanumeric symbols can be used as identification marks to identify a tube (vessel 2) (see figures 1a, 2a, and column 3 lines 2-10).

In view of Erb et al's teachings, it would have been obvious to one of ordinary skill in the art at the time of the invention to include, with the method as taught by Sodickson et al, wherein the array of information comprising a magnetic stripe, said step of reading said information comprising passing said tube in proximity to a magnetic reader for reading said information; wherein the array of information comprises a bar code, said step of reading said information comprising optically scanning said code; wherein said bar code is a linear bar code or a two dimensional dot matrix maxicode, since magnetic stripes and bar codes are art recognized functional equivalents for the purpose of identifying tubes.

### ***Response to Arguments***

7. Applicant's arguments filed 3/22/2004 have been fully considered but they are not persuasive.

In response to applicant's argument that Sodickson et al states that a specimen from the patient is drawn into a specimen container having a blank label area, after which the tube is inserted into the apparatus where the label is impressed with the encoded patient identification data (see pages 5-6, of the amendment filed on 3/22/2004); and the specimen container in Sodickson et al already contains the specimen when the label is encoded (see page 6, of the amendment filed on 3/22/2004), it is noted that applicants have not pointed to any specific column or line in the Sodickson et al reference that states that the specimen/sample is placed in the tube prior to writing the patient identification information to the label on the tube. The examiner respectfully requests that applicants identify the specific teachings in the Sodickson et al reference upon which they are relying.

Furthermore, Sodickson et al states, "Once the label is complete and the specimen is drawn, the tube (and additional card if used) are delivered to the processing laboratory." (see column 1, lines 69-71). This suggests that the patient identification information is written to the label prior to placing the specimen/sample in the tube.

In response to applicant's argument that Sodicksone et al discloses a single piece of apparatus (see page 6, of the amendment filed on 3/22/2004), Sodickson et al states, "Once the label is complete and the specimen is drawn, the tube (and additional card if used) are delivered to the processing laboratory. The sample container can then be keyed into a device which decodes the marks previously transcribed onto the tube and transfers the identification and other information into storage in a data processing

system.” (see column 1, lines 69-74). Sodickson et al also states, “Similar scanning apparatus and logical apparatus may be used at the input to individual test instruments to recover the identification information encoded on the label and correlate this information with the results of the analytical procedure on the specimen in the test tube 15.” (see column 3, lines 42-46). Clearly this teaches a laboratory apparatus, distinct from the label encoder, for reading the identification information on the tube.

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

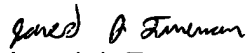
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jared J. Fureman whose telephone number is (571) 272-2391. The examiner can normally be reached on 7:00 am - 4:30 PM M-T, and every other Friday.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on (571) 272-2398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jared J. Fureman  
Examiner  
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April 5, 2004